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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,888	10/19/2004	Dirk Cremer	5942/83518	4210

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	
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09/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,888	CREMER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-12,15,16 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-12,15,16 and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt request for extension of time, request for continued examination under 37 CFR 1.114, amendment, remarks and declaration under 37 CFR 1.132, all filed 7/20/09. The examiner further acknowledges receipt of certified copy of priority document DE 102 50 727.9 filed 7/24/09. Claims 1, 2, 5-7 and 20-24 are amended. Claims 1-3, 5-12, 15, 16 and 18-24 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/20/09 has been entered.

Response to Arguments

2. Previous rejections that are not reiterated herein are withdrawn in view of applicant's amendment to claims 1, 2, 5 and 20-23 and applicant's persuasive arguments that Kiliaan's composition does not contain a wax and that the compositions of Morrison and Haynes are containing the phospholipids are not encapsulated while the phospholipids are encapsulated in the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 15, 16 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680).

6. Kiliaan discloses a capsule containing phospholipid comprised of phosphatidyl serine and phosphatidyl choline; the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; the composition meeting the limitations of claims 1-3, 5, 15, 16 and 20-23 in the sense that phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids meeting the percent limitation in claim 2; the DHA and EPA omega fatty acids meet the fractionated fat of claim 5.

The composition of Kiliaan is administered to treat vascular disorders/dementia syndromes (page 1, lines 6-9) meeting claim 15. On page 6, lines 21-30, Kiliaan discloses that the composition of contains eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), arachidonic acid at a ratio of EPA +DHA to DHGLA +AA of 2.5 to 5.5%, or mixtures. EPA and DHA are fat and phospholipids are also fats. In Example 1, the amount of the fat is at (50 + 75 + 250)/830.3 = ~45% meeting the requirements of the limitation of 20-50% fat in claims 1 and 20-22. The phosphatidyl serine at 14.4% anticipates the requirement that the phosphatidyl serine be at a range of 10-40% in claims 1 and 20-22, 15-30% in claims 2, 16 and 23. The phosphatidyl choline at 15.6% anticipates the requirement that the phosphatidyl choline be at a range of 1-90% in claims 1 and 20-22, 2.0-20% in claims 3 and 23. The presence of fat (the omega fatty acids and the phospholipids) and vitamins (Example 1 and claims 10 and 11) meet the requirement for the presence of broad fat and additives in claim 5.

7. The composition of Kiliaan does not contain wax. But della Valle discloses composition comprising phosphatidyl serine, phosphatidylethanolamine or phosphatidylcholine and beeswax (abstract; column 2, lines 29-38; column 9, lines 54-63); the composition is used for the treatment of pathologies such as vascular complications from old age and dementia (column 5, lines 50-59).

8. Kiliaan uses the composition to treat vascular disorders including dementia. The composition of della Valle is also used to treat dementia. Therefore, taking the combined teachings of Kiliaan ands della Valle, one having ordinary skill in the art at the time the invention was made would have reasonably expected that a third composition derived from the combination of the composition of Kiliaan and della Valle would be effective in treating

dementia. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

9. Claims 1-3, 5, 15, 16, 19 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680) and further in view of Patel et al. (US 6,294,192).

10. Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680) has been described to render claims 1-3, 15, 16 and 20-23 obvious.

11. The DHA and EPA listed in the composition of Example 1 of Kiliaan meet the compositional requirement of claim 19. The combined composition of Kiliaan and della Valle does not contain the polyol recited in claim 5. However, hydrophobic active agents have been known to be solubilized by surfactants. For example, the phospholipids, phosphatidyl choline and phosphatidyl serine are hydrophobic.

12. Patel uses mixtures of hydrophilic surfactant and hydrophobic surfactant to solubilize hydrophobic agents (abstract; columns 5 and 6) and also suggests that solubilizers such as alcohols and polyols, namely, ethanol, ethylene glycol, polyethylene glycol (column 25, lines 14-54) can also be included in the compositions as solubilizing agents. Therefore, taking the teaching of Kiliaan and Patel, one having ordinary skill in the art at the time the invention was made would have reasonable expectation that including polyethylene glycol or in combination

with any of the other solubilizers would solubilize the phosphatidyl serine and phosphatidyl choline for effective delivery.

13. Claims 1, 6-12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680) and further in view of Winston, Jr. et al. (US 5,342,626).

14. Kiliaan in view of della Valle has been described above to render claim 1 obvious. The combined composition does not have encapsulating material to have water required by claim 6.

15. But, Winston, Jr. discloses that gelatin polymers and non-gelatin materials can be used in encapsulation, that these polymers such as gellan gum, carrageenan and mannan gum re-melt under controlled conditions to form soft capsules that seal encapsulated contents (see the entire document with emphasis on the abstract, column 1, lines 7-12 and 62-68; column 2, lines 9-18). The %water in capsule after solvent removal and drying is at a predetermined amount of 3-4% (column 4, lines 59-65; column 7, lines 51-55). The gelatin free capsule shell of Winston, Jr. further comprises plasticizers selected form sorbitol, glycerin, propylene glycol, corn syrup, sucrose, fructose and polyethylene glycol and mixtures (column 4, lines 42-47; claim 3). The carrageenans and sorbitol meet claims 8 and 9. The capsule of Winston, Jr. may also contain dyes (column 8, lines 12, 13) so that claim 10 is met. Winston, Jr. teaches that the water insoluble liquids are microencapsulated, that the encapsulation masks the taste of unpleasant tasting compositions and further protects oxidation of these compositions and allows for controlled release of these compositions (column 8, lines 14-19). Thus, with regards to claim 11, one having ordinary skill in the art would be motivated to use amounts of the coating or encapsulating material relative to the composition that would provide effective masking of the

taste, provide the desired controlled release of the composition and be also effective in protecting the composition from oxidation so that the ratio of the coating to the bioactive agent would be obvious. The 3-4% moisture content of the capsule shell anticipates the water/moisture content of 1.0 to 10.0% of claim 7. Since Winstson, Jr. contemplates microencapsulation or microcapsules and because microcapsules would have diameters in the micrometer range, the microcapsule of Winston would be expected to fall within the diameter recited in claim 12. There is no demonstration that the recited diameter of the matrix provides unexpected results.

16. Therefore, taking the teaching of Kiliaan et al. (WO 0184961) and della Valle et al. (US 4,595,680) and Winston, Jr. et al. (US 5,342,626), one having ordinary skill in the art at the time the invention was made would reasonably expect that the presence of moisture in the capsule would effectively control the melting temperature and proper sealing of the capsules.

17. Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961) in view of della Valle et al. (US 4,595,680) and further in view of Winston, Jr. et al. (US 5,342,626).

18. Kiliaan in view of della Valle has been described above to render claim 22 obvious. The combined composition does not have encapsulating material to have water required by claim 24.

19. But, Winston, Jr. discloses that gelatin polymers and non-gelatin materials can be used in encapsulation, that these polymers such as gellan gum, carrageenan and mannan gum re-melt under controlled conditions to form soft capsules that seal encapsulated contents (see the entire document with emphasis on the abstract, column 1, lines 7-12, 62-68; column 2, lines 9-18). The %water in capsule after solvent removal and drying is at a predetermined amount of 3-4%

(column 4, lines 59-65; column 7, lines 51-55). The gelatin free capsule shell of Winston, Jr. further comprises plasticizers selected form sorbitol, glycerin, propylene glycol, corn syrup, sucrose, fructose and polyethylene glycol and mixtures (column 4, lines 42-47; claim 3). The carrageenans and sorbitol meet the components of claim 24. Winston, Jr. teaches that the water insoluble liquids are microencapsulated, that the encapsulation masks the taste unpleasant tasting compositions and further protects oxidation of these compositions and allows for controlled release of these compositions (column 8, lines 14-19).

20. Therefore, taking the teaching of Kiliaan et al. (WO 0184961) and della Valle et al. (US 4,595,680) and Winston, Jr. et al. (US 5,342,626), one having ordinary skill in the art at the time the invention was made would reasonably expect that the presence of moisture in eth capsule would effectively control the melting temperature and proper sealing of the capsules.

Response to Arguments

21. Applicant's arguments filed 7/20/09 have been fully considered but they are not persuasive.

22. Applicant argues that the composition of Kiliaan does not contain wax. The examiner agrees and that is why the rejection under 35 USC 102 has been dropped in favor of rejections under 35 USC 103 in view of the current amendment.

23. Applicant argues that stable matrix would not be formed when the amounts of fatty acids in Example 1 of Kiliaan are used so that the composition of Kiliaan would provide the properties and stability described and sought in the instant "application." The examiner disagrees. Applicant has not provided factual evidence to show that stable matrix cannot be formed and that

the composition does not have the disclosed properties. Furthermore, limitations such as stability and any properties cannot be imported form the specification. Also, Kiliaan does not disclose the composition is unstable.

24. Applicant further argues that the composition Kiliaan contains herbal extracts. But, while that may be so, the comprising language of the claims is open and does not exclude the extracts.

25. Declaration by Dr. Dirk Cremer:

26. The declaration under 37 CFR 1.132 re-filed 7/20/09 is insufficient to overcome the rejection of claims 1-3, 5-12, 15, 16 and 18-24 based upon 35 USC 103 as set forth currently in this Office action herein because: a) the declaration is an opinion declaration providing no empirical evidence as to why the claimed composition is unexpected over the disclosed composition of the prior art; b) in paragraphs 6 and 7 of the declaration, it is said that the composition of Kiliaan does not contain wax, but the rejection has been made over Kiliaan in view of della Valle and Winston, Jr. and Patel in view of the amendment to the claims where the wax is positive requirement and not optional; c) the opinion in the declaration that the composition of Kiliaan cannot form a solid matrix at room temperature cannot take the place of factual evidence in the record.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618